

Food and Drug Administration, HHS

§ 882.4030

§ 882.1835 Physiological signal amplifier.

(a) *Identification.* A physiological signal amplifier is a general purpose device used to electrically amplify signals derived from various physiological sources (e.g., the electroencephalogram).

(b) *Classification.* Class II (performance standards).

§ 882.1845 Physiological signal conditioner.

(a) *Identification.* A physiological signal conditioner is a device such as an integrator or differentiator used to modify physiological signals for recording and processing.

(b) *Classification.* Class II (performance standards).

§ 882.1855 Electroencephalogram (EEG) telemetry system.

(a) *Identification.* An electroencephalogram (EEG) telemetry system consists of transmitters, receivers, and other components used for remotely monitoring or measuring EEG signals by means of radio or telephone transmission systems.

(b) *Classification.* Class II (performance standards).

§ 882.1870 Evoked response electrical stimulator.

(a) *Identification.* An evoked response electrical stimulator is a device used to apply an electrical stimulus to a patient by means of skin electrodes for the purpose of measuring the evoked response.

(b) *Classification.* Class II (performance standards).

§ 882.1880 Evoked response mechanical stimulator.

(a) *Identification.* An evoked response mechanical stimulator is a device used to produce a mechanical stimulus or a series of mechanical stimuli for the purpose of measuring a patient's evoked response.

(b) *Classification.* Class II (performance standards).

§ 882.1890 Evoked response photic stimulator.

(a) *Identification.* An evoked response photic stimulator is a device used to

generate and display a shifting pattern or to apply a brief light stimulus to a patient's eye for use in evoked response measurements or for electroencephalogram (EEG) activation.

(b) *Classification.* Class II (performance standards).

§ 882.1900 Evoked response auditory stimulator.

(a) *Identification.* An evoked response auditory stimulator is a device that produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.

(b) *Classification.* Class II (performance standards).

§ 882.1925 Ultrasonic scanner calibration test block.

(a) *Identification.* An ultrasonic scanner calibration test block is a block of material with known properties used to calibrate ultrasonic scanning devices (e.g., the echoencephalograph).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38807, July 25, 2001]

§ 882.1950 Tremor transducer.

(a) *Identification.* A tremor transducer is a device used to measure the degree of tremor caused by certain diseases.

(b) *Classification.* Class II (performance standards).

Subparts C–D [Reserved]

Subpart E—Neurological Surgical Devices

§ 882.4030 Skull plate anvil.

(a) *Identification.* A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in

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subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4060 Ventricular cannula.

(a) *Identification.* A ventricular cannula is a device used to puncture the ventricles of the brain for aspiration or for injection. This device is frequently referred to as a ventricular needle.

(b) *Classification.* Class I (general controls). When made only of surgical grade stainless steel, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 65 FR 2319, Jan. 14, 2000]

§ 882.4100 Ventricular catheter.

(a) *Identification.* A ventricular catheter is a device used to gain access to the cavities of the brain for injection of material into, or removal of material from, the brain.

(b) *Classification.* Class II (performance standards).

§ 882.4125 Neurosurgical chair.

(a) *Identification.* A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4150 Scalp clip.

(a) *Identification.* A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp.

(b) *Classification.* Class II (performance standards).

§ 882.4175 Aneurysm clip applicator.

(a) *Identification.* An aneurysm clip applicator is a device used by the surgeon for holding and applying intracranial aneurysm clips.

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(b) *Classification.* Class II (performance standards).

§ 882.4190 Clip forming/cutting instrument.

(a) *Identification.* A clip forming/cutting instrument is a device used by the physician to make tissue clips from wire stock.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994]

§ 882.4200 Clip removal instrument.

(a) *Identification.* A clip removal instrument is a device used to remove surgical clips from the patient.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4215 Clip rack.

(a) *Identification.* A clip rack is a device used to hold or store surgical clips during surgery.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4250 Cryogenic surgical device.

(a) *Identification.* A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site.

(b) *Classification.* Class II (performance standards).

§ 882.4275 Dowel cutting instrument.

(a) *Identification.* A dowel cutting instrument is a device used to cut dowels of bone for bone grafting.

(b) *Classification.* Class II (performance standards).